CALIFORNIA CODES
FOOD AND AGRICULTURAL CODE
SECTION 13121-13135

13121. This article shall be known and may be cited as the Birth Defect Prevention Act of 1984.

13122. It is the purpose of the Legislature in enacting this chapter to prevent pesticide induced abortions, birth defects, and infertility.

13123. For purposes of this chapter, the following terms mean: (a) "Adverse reproductive effect" means a statistically significant adverse effect on parental reproductive performance and the growth and development of offspring, including gonadal function, conception, and parturition; abortions; birth defects; stillbirths; and resorptions.

(b) "Data gap" means that the department does not have on file a full set of valid mandatory health effects studies.

(c) "Mandatory health effects study" means adverse reproductive effect, chronic toxicity, mutagenicity, neurotoxicity, oncogenicity, and teratogenicity studies required for full registration or licensing of pesticides in California, as of July 1, 1983.

(d) "Teratogenic" means the property of a substance or mixture of substances to produce or induce functional deviations or developmental anomalies, not heritable, in or on an animal embryo or fetus.

(e) "Mutagenic effect" means the property of a substance or mixture of substances to induce changes in the genetic complement of either somatic or germinal tissue in subsequent generations.

(f) "Chronic toxicity" means the property of a substance or mixture of substances to cause adverse effects in an organism upon repeated or continuous exposure over a period of at least one-half the lifetime of that organism.

(g) "Oncogenic" means the property of a substance or a mixture of substances to produce or induce benign or malignant tumor formations in living animals.

(h) "Neurotoxic effect" means any adverse effect on the nervous system such as delayed-onset locomotor ataxia resulting from single administration of the test substance, repeated once if necessary.

(i) "Initiation" means that the mandatory health effects study or any necessary preliminary studies, such as pilot studies or range finding studies, have been commenced.

(j) "Data generator" means a person who has completed and filed with the director a data commitment status report.

(k) "Completion" means that the study has been finished, the data has been analyzed, and the final report of the results, including all exhibits, has been prepared and submitted to the department.

(l) "Submitted" means deliverance of a completed study to the department. A study shall be deemed to be submitted until it has been determined by the department to be unacceptable and not capable of being upgraded.

(m) "Suspend" means the director has issued a notice of intent to suspend the registration of a pesticide product. The director shall issue a suspension order at the earliest possible time.

13123.5. To the extent feasible, health effects studies shall be conducted in accordance with standards and protocols established pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. Sec. 135 et seq.).

13126. No new active pesticide ingredient shall be conditionally registered or licensed when any of the mandatory health effects studies, as defined in subdivision (c) of Section 13123, is missing, incomplete, or of questionable validity unless the registration is based on previous consultation with the State Director of Health Services and the Director of Industrial Relations.

13127.

(a) Not later than December 31, 1985, the department shall identify 200 pesticide active ingredients which the department determines have the most significant data gaps and widespread use and which are suspected to be hazardous to people. Not later than 30 days after the report issued pursuant to former Section 13125, as added by Chapter 669 of the Statutes of 1984, the department shall notify each registrant of a pesticide product containing any of the identified 200 pesticide active ingredients of the applicable data gap required to be filled pursuant to this section.

(b) Not later than December 31, 1985, the department shall also adopt a timetable for the filling of all data gaps on all pesticide active ingredients, other than those identified by the department pursuant to subdivision (a), which are currently registered or licensed in California. The department shall notify registrants of the applicable data gaps and the scheduled time to initiate and complete studies as provided in the timetable.

(c)

(1) Not later than September 1, 1986, the department shall determine whether a test has been initiated to fill each of the data gaps for each pesticide active ingredient identified in subdivision (a). If no test has been initiated, the department shall fill data gaps in accordance with procedures provided in subparagraph (B) of paragraph (2) of subsection (c) of Section 136a of Title 7 of the United States Code. In order to carry out this section, the director has the same authority to require information from registrants of active pesticide ingredients and to suspend registration that the Administrator of the Environmental Protection Agency has pursuant to subparagraph (B) of paragraph (2) of subsection (c) of Section 136a of Title 7 of the United States Code. If a hearing is requested regarding the proposed suspension of registration, it shall be conducted pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code. On or before July 1, 1986, the director shall, by regulation, prescribe procedures for resolving disputes or funding the filling of data gaps. The procedures may include mediation and arbitration. The arbitration procedures, insofar as practical, shall be consistent with the federal act, or otherwise shall be in accordance with the commercial arbitration rules established by the American Arbitration Association. The procedures shall be established so as to resolve any dispute within the timetable established in subdivision (a).

(2) The department shall also obtain the data which is identified in subdivision (b), according to the timetable and procedures specified in this section.

(d) The director shall review the timetable established by the Environmental Protection Agency for the accelerated registration program under amendments effective in 1989 to the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. Sec. 136 et seq.).

(e)

(1) This section does not apply to any product which the director determines has limited use or that substantial economic hardship would result to users due to unavailability of the product and there is not significant exposure to the public or workers and the product is otherwise in compliance with federal law.

(2) The director may not, pursuant to this subdivision, exempt all pesticide products containing the same pesticide active ingredient unless it is determined that the pesticide active ingredient has only limited use, there is insignificant exposure to workers or the public, and the products are otherwise in compliance with federal law. Any exemption issued pursuant to this paragraph shall expire at the end of three years after it is issued.

(f)

(1) Whenever the director exercises the authority provided in paragraph (1) of subdivision (e), he or she shall give public notice of the action stating the reasons for exempting the pesticide product from the data requirements of this article. Copies of this notice shall be provided to the appropriate policy committees of the Legislature.

(2) Whenever the director acts pursuant to paragraph (2) of subdivision (e), the director shall furnish not less than 30 days' public notice of the proposed action, stating the reasons for exempting the pesticide product from the data requirements of this article and allowing public comment thereon. Copies of the notice and the final decision shall be provided to the appropriate policy committees of the Legislature.

13127.2. The director shall, on January 15, 1992, issue a notice of the impending suspension of the registration of any pesticide product containing an active ingredient identified pursuant to subdivision (a) of Section 13127 for which the registrant has not submitted the required data by December 31, 1991. The data generator or registrant may petition the director within 30 days of notification of impending suspension of registration for deferral of the suspension pursuant to Section 13127.3. The director shall act upon such a petition at the earliest possible time and, upon denial of the petition, suspend the registration of each such product.

13127.3.

(a) The director shall grant an extension of time for submission of the required data if, and only if, the director, with the concurrence of the Secretary for Environmental Protection, makes a finding that both of the following conditions are satisfied:

(1) The registrant has submitted at least eight of the mandatory health effects studies, and has initiated the studies required to fill the remaining data gaps by January 15, 1992, unless the registrant can demonstrate to the satisfaction of the director that it failed to have eight studies submitted, and the remaining studies initiated, in accordance with this paragraph because not more than two studies were delayed due to specific, written direction of the department based upon a written evaluation by a department toxicologist.

(2) That the registrant has taken appropriate steps to meet the requirements of this article. To determine whether appropriate steps have been taken, the director shall consider the registrant's timely response to data call-ins on other active ingredients contained in products registered with the department pursuant to this article and pursuant to Article 15 (commencing with Section 13141), and whether the registrant has responded in a timely and appropriate manner to notices and correspondence from the department relating to data call-ins and has taken appropriate measures to address study deficiencies identified by the department.

(b) A registrant shall not be considered to have taken the appropriate steps, as provided in subdivision (a), if the registrant has failed to meet the deadlines established by this article due to efforts to coordinate compliance with federal data requirements.

13127.31. Notwithstanding subdivision (a) of Section 13127.3, if the director finds that delays in submitting the mandatory health effects studies were primarily caused by actions of the department, the director, with the concurrence of the Secretary for Environmental Protection, may extend the deadlines for submitting the mandatory health effects studies for the following active ingredients creosote, pentachlorophenol, dicamba, para-dichlorobenzene, methyl bromide, napropamide, petroleum distillates, and arsenic pentoxide/trioxide. Registrants of these products shall submit the required studies in a timely manner, but in no case later than the time allowed in Section 13127.92.

13127.32. Notwithstanding any other provision of law, none of the following pesticide products shall remain registered in this state:

(a) Except as specified in subdivision (b), no pesticide product containing an active ingredient identified pursuant to subdivision (a) of Section 13127 for which the required studies have not been submitted by March 30, 1996, shall remain registered after that date.

(b) No pesticide product containing methyl bromide or pentachlorophenol for which the required studies have not been submitted by December 31, 1997, shall remain registered after that date.

13127.5. (a) The director, with the concurrence of the Secretary for Environmental Protection, may defer the suspension of registration of a pesticide product, as provided in Section 13127.2, if both of the following occur:

(1) The director receives a petition from the registrant or any other person requesting a deferral of suspension.

(2) The director makes a written finding of one of the following:

(A) Suspension of the registration of the product would cause substantial economic hardship to the users of the product, that there would be no significant, unmitigated human exposure to the product, and that no feasible alternatives to the product are available.

(B) Suspension of the registration of the product would be more detrimental to the agricultural or nonagricultural environment than continued use of the product, that there would be no significant, unmitigated human exposure to the product, and that no feasible alternatives to the product are available.

(C) Suspension of the registration of the product would result in significant risk to the public health and that no feasible alternatives to the product are available.

(b) The director shall limit the use of any product granted a deferral of suspension pursuant to paragraph (2) of subdivision (a) to specific uses that conform to the director's findings pursuant to paragraph (2) of subdivision (a).

13127.6. The director shall levy a charge on data generators of up to one thousand dollars ($1,000) per day for each day a data gap continues to exist after the date the director issues a deferral of suspension of registration pursuant to Section 13127.5. In establishing the amount of

the charge, the director shall consider the number of outstanding studies, the registrant's timely response to data call-ins on other products registered with the department pursuant to this article, and whether the registrant has responded in a timely and appropriate manner to notices and correspondence from the department relating to data call-ins, and whether the registrant has taken appropriate measures to address study deficiencies identified by the department. If the charge levied on the data generator is not paid, all products containing that active ingredient shall be suspended. Revenues collected from the levying of charges shall be deposited in the Department of Pesticide Regulation Fund.

13127.7. All documentation relevant to a finding made pursuant to Sections 13127.3 and 13127.5 shall be available to the public, and the findings shall be a public record.

13127.8. (a) A suspension of registration of a pesticide product containing any of the active ingredients identified pursuant to subdivision (a) of Section 13127 shall be revoked when the director determines that the registrant has submitted all of the mandatory health effects studies. If, upon completion of the review of the studies, the director determines that a data gap still exists, the director shall suspend the registration.

(b) If at any time after January 1, 1992, the registrant meets the requirements of subdivision (a) of Section 13127.3, notwithstanding the date specified in paragraph (1) of subdivision (a) of Section 13127.3, the director shall revoke the suspension, and shall levy a charge pursuant to Section 13127.6 or, if a charge has already been levied on a registrant, the director may revise the charge in light of the registrant's compliance with the requirements of this article and Article 15 (commencing with Section 13141).

(c) The director may modify the amount of the charge levied pursuant to Section 13127.6 upon the initiation or submission of any health effects studies required pursuant to this article.

13127.9. For each mandatory health effects study that is required for each active ingredient identified pursuant to subdivision (a) of Section 13127, the registrant shall submit to the department a progress report in December of each year until the study is completed.

13127.91. The director shall suspend the registration of any pesticide product that contains an active ingredient identified pursuant to subdivision (a) of Section 13127 for which the registrant fails to do any of the following:

(a) Respond to the director's notification of a data gap.

(b) Submit progress reports as required by Section 13127.9.

(c) Demonstrate reasonable progress toward completion of all the mandatory health effects studies.

13127.92. (a) Extensions of time granted pursuant to Section 13127.3, 13127.31, and 13127.5 shall only be for the time necessary to complete the mandatory health effects studies.

(b) Mandatory health effects studies shall be completed in accordance with the following timetable:

(1) Forty-eight months for oncogenicity, chronic feeding, and reproduction studies.

(2) Twenty-four months for teratogenicity and neurotoxicity studies.

(3) Twelve months for mutagenicity studies.

(c) A deferral of suspension of registration issued pursuant to Section 13127.5 shall be subject to an annual review by the director and shall be limited to the time necessary to compete the required studies, and shall in no case exceed four years with the time tolling from the date that the registrant petitioned for an extension.

(d) Any extension of time for submission of the mandatory health effects studies granted pursuant to Section 13127.5 shall be canceled by June 15, 1993, and the registration suspended for the affected ingredient, if the registrant fails to initiate the required studies by June 15, 1992.

13128. No applicant for registration or current registrant of a pesticide who proposes to purchase or purchases a registered pesticide from another producer in order to formulate the purchased pesticide into an end use product shall be required pursuant to Section 13127 to submit or cite mandatory health effect data pertaining to the safety of the purchased product or to offer to pay reasonable compensation for the use of any such data if the producer is engaged in fulfilling the requirements of Section 13127.

13129. (a) If the director, after evaluation of the health effects study of an active ingredient, finds that a pesticide product containing the active ingredient presents significant adverse health effects, including reproduction, birth defects, or infertility abnormalities, the director shall take cancellation or suspension action against the product pursuant to Section 12825 or 12826.

(b) The State Director of Health Services shall have access to mandatory health effects studies and other health effects studies on file at the Department of Food and Agriculture, and may, based upon the determination of the State Director of Health Services, provide advice, consultation, and recommendations concerning the risks to human health associated wth exposure to the substances tested.

13130.3. (a) Notwithstanding subdivision (b) of Section 13127, the time permitted by the director for submitting data to fill a data gap shall be as follows:

(1) For oncogenicity studies and chronic feeding studies, 48 months.

(2) For reproduction studies, 48 months.

(3) For teratogenicity and neurotoxicity studies, 24 months.

(4) For mutagenicity studies, 12 months.

The time permitted by the director for submitting data to fill a data gap shall commence upon the date the department notifies the registrant of the data gap.

(b) Notwithstanding the time limit established in subdivision (a) for submitting data to fill a data gap, the department may, with the concurrence of the Office of Environmental Health Hazard Assessment, grant an extension of time to complete the required studies, upon a written finding that events beyond the control of the persons responsible for submitting the data prevent submission of the data within the prescribed time, and that those persons have made a good faith effort to complete the studies within the prescribed time. Not more than one extension of time per data requirement may be granted to complete the required studies. The length of an extension granted pursuant to this subdivision shall be limited to the time necessary to complete the studies, not to exceed the length of time specified in subdivision (a) for conducting the studies.

13131.1. (a) Not later than March 1, 1992, the director shall notify registrants of the data requirements, and the guidelines the director intends to use in reviewing studies submitted

pursuant to subdivision (b) of Section 13127, for all pesticide active ingredients other than those identified pursuant to subdivision (a) of Section 13127.

(b) Not later than 90 calendar days after the date of notification of the data requirements, each registrant shall do one of the following:

(1) Inform the department, in a manner prescribed by the director, of how the registrant will comply with the data requirements.

(2) File a written objection, accompanied by any supporting evidence and arguments, to all or part of the director's notice of data requirements. The objection authorized by this paragraph shall be the exclusive opportunity for a registrant to object to the director's notice of data requirements.

(c) The director may consider and grant a request by a registrant to initiate the studies necessary to comply with the data requirements in accordance with a schedule established by the United States Environmental Protection Agency. In no event shall a registrant be authorized pursuant to this subdivision to initiate the studies necessary for that compliance after January 1, 1994.

13131.2. (a) Prior to March 1, 1992, or in response to a written objection filed pursuant to paragraph (2) of subdivision (b) of Section 13131.1, the department may determine, with the concurrence of the Office of Environmental Health Hazard Assessment, that one or more of the mandatory health effects studies are not required in order to evaluate pesticide active ingredients other than those identified pursuant to subdivision (a) of Section 13127. This determination may be made only in accordance with one or more of the following criteria:

(1) The ingredient has been classified as "Generally Recognized as Safe" by the United States Food and Drug Administration.

(2) The study is not physically possible due to the nature of the ingredient.

(3) The department has on file toxicological data that is adequate for the assessment of the potential adverse health effects of the ingredient, and the studies relied upon for that purpose are of the same study type, are scientifically valid, and, when taken together, are of a power and sensitivity equivalent to the studies that would be waived pursuant to this subdivision.

(b) The director may, in conjunction with the Office of Environmental Health Hazard Assessment, develop regulations for modification of mandatory health effects studies.

13131.3. If the Office of Environmental Health Hazard Assessment does not concur with the determination of the department pursuant to Section 13131.2, the issue shall be decided by a majority of the membership of a panel consisting of the following persons:

(a) An appointee of the State Director of Health Services who has expertise in toxicology.

(b) An appointee of the President of the University of California who has expertise in toxicology.

(c) An appointee of the Secretary for Environmental Protection who has expertise in toxicology.

13131.4. (a) On or before January 1, 1994, the director shall issue a final notice of data gaps required to be filled for all pesticide active ingredients other than those identified pursuant to subdivision (a) of Section 13127. This notice shall be the department's final determination of the data gaps required to be filled.

(b) The time allowed under Section 13130.3 to fill the data gaps shall commence on the date that the final notice of data gaps is issued pursuant to subdivision (a), unless an extension is granted pursuant to subdivision (b) of Section 13130.3.

(c) Not later than 90 calendar days after the date the final notice of data gaps is issued pursuant to subdivision (a), each registrant shall inform the department, in a manner prescribed by the director, how the registrant will fill the data gap, including a proposed schedule for initiation, completion, and submittal of all required studies.

13131.5. The director shall suspend the registration of any pesticide containing an active ingredient for which the director notifies a registrant pursuant to Section 13131.1 and for which the registrant or data generator, in the judgment of the director, fails to respond appropriately or fails to provide evidence that it is taking appropriate steps to secure the data that are required pursuant to Section 13131.1 or the final notice of data gaps pursuant to Section 13131.4.

13133. If any provision of this article or the application thereof to any person or circumstances is held invalid, this invalidity shall not affect other provisions or applications of the article which can be given effect without the invalid provision or application, and to this end the provisions of this article are severable.

13134. (a) The department, in cooperation with the State Department of Health Services, shall conduct an assessment of dietary risks associated with the consumption of produce and processed foods treated with pesticides. This assessment shall integrate adequate data on acute effects and the mandatory health effects studies specified in subdivision (c) of Section 13123, appropriate dietary consumption estimates, and relevant residue data based on the department's and the State Department of Health Services' monitoring data and appropriate field experimental and food technology information to quantify consumer risk. Differences in age, sex, ethnic, and regional consumption patterns shall be considered. The department shall submit each risk assessment to the State Department of Health Services, with necessary supporting documentation, for peer review, which shall consider the adequacy of public health protection. The State Department of Health Services may provide comments to the department. The department shall formally respond to all of the comments made by the State Department of Health Services. The department shall modify the risk assessment to incorporate the comments as deemed appropriate by the director. All correspondence between the department and the State Department of Health Services in this matter shall be made available to any person, upon request, pursuant to the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code).

(b) The department shall consider those pesticides designated for priority food monitoring pursuant to Section 12535 and the results of the department's or the State Department of Health Services' monitoring in establishing priorities for the dietary risk assessments.

(c) (1) If the department lacks adequate data on the acute effects of pesticide active ingredients or mandatory health effects studies specified in subdivision (c) of Section 13123 necessary to accurately estimate dietary risk, the department shall require the appropriate data to be submitted by the registrant of products whose labels include food uses. This subdivision shall not be construed to affect the timeframes established pursuant to Section 13127.

(2) No applicant for registration, or current registrant, of a pesticide who proposes to purchase or purchases a registered pesticide from another producer in order to formulate the purchased pesticide into an end use product shall be required to submit or cite data pursuant to this section

or offer to pay reasonable compensation for the use of any such data if the producer is engaged in fulfilling the data requirements of this section.

(d) (1) If a registrant fails to submit the data requested by the director pursuant to this section within the time specified by the director, the director shall issue a notice of intent to suspend the registration of that pesticide. The director may include in the notice of intent to suspend any provisions that are deemed appropriate concerning the continued sale and use of existing stocks of that pesticide. Any proposed suspension shall become final and effective 30 days from the receipt by the registrant of the notice of intent to suspend, unless during that time a request for hearing is made by a person adversely affected by the notice or the registrant has satisfied the director that the registrant has complied fully with the requirements that served as a basis for the notice of intent to suspend. If a hearing is requested, a hearing shall be conducted pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code. The only matter for resolution at the hearing shall be whether the registrant has failed to take the action that served as the basis for the notice of intent to suspend the registration of the pesticide for which additional data is required and whether the director's determination with respect to the disposition of existing stocks is consistent with this subdivision.

(2) A hearing shall be held and a determination made within 75 days after receipt of a request for a hearing. The decision rendered after completion of the hearing shall be final. Any registration suspended shall be reinstated by the director if the director determines that the registrant has complied fully with the requirements that served as a basis for the suspension of the registration.

(e) If the department finds that any pesticide use represents a dietary risk that is deleterious to the health of humans, the department shall prohibit or take action to modify that use or modify the tolerance pursuant to Section 12561, or both, as necessary to protect the public.

13135. The department and the State Department of Health Services shall jointly review the existing federal and state pesticide registration and food safety system and determine if the existing programs adequately protect infants and children from dietary exposure to pesticide residues. The review shall commence as early as possible in 1990, so that any policy or administrative adjustments determined to be necessary as a result of the joint review can be made on a timely basis. The department shall consult with the University of California and other qualified public and private entities in conducting the joint review. The joint review shall continue for a sufficient time in order to evaluate the report of infant exposure to pesticide residues, which is presently being undertaken by the National Academy of Sciences. Within six months of the official release of the National Academy of Sciences' study, the department shall finalize a report describing the evaluation that was conducted pursuant to this section, including any recommendations for modification of the existing regulatory system in order to adequately protect infants and children.